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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/627,780

07/28/2003

Kejun Fan

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05/31/2006

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EXAMINER

KIM, YOUNG J

ART UNIT

PAPER NUMBER

1637

DATE MAILED: 05/31/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/627,780	Applicant(s) FAN, KEJUN	
	Examiner Young J. Kim	Art Unit 1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 March 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

The present Office Action is responsive to the Amendment received on March 16, 2006.

Preliminary Remark

No claims have been canceled.

Claims 8-22 are new.

Claims 1-22 are pending and are under prosecution therefore.

The present Office Action contains at least one rejection which is not necessitated by Amendment, and therefore, is made **Non-Final**.

Claim Rejections - 35 USC § 112

The rejection of claims 1-6 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter, made in the Office Action mailed on January 13, 2006 is withdrawn in view of the Amendment received on March 16, 2006.

Rejection, New Grounds

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 6 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 6 is indefinite for reciting the phrase, "eluting the nucleic acids adsorbed onto the solid phase carrier," because the nucleic acids are already adsorbed onto the solid phase carrier in claims 1 and 5. Hence, it is unclear how the nucleic acids are eluted onto the solid phase carrier.

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For the purpose of examination the claim is construed to mean that the solid phase carriers comprising the nucleic acids adsorbed thereto, are eluted.

Claim Rejections - 35 USC § 102

The rejection of claims 1-7 under 35 U.S.C. 102(b) as being anticipated by Dzieglewska et al. (WO 96/18731, published June 20, 1996; IDS ref # AS) made in the Office Action mailed on January 13, 2006 is withdrawn in view of the arguments presented in the Amendment received on March 16, 2006. Specifically, Dzieglewska et al. do not disclose the step of bringing the sample containing nucleated cells into contact with a water-insoluble solid-phase carrier in the presence of a water-soluble organic solvent, thereby failing to teach all of the claimed limitations.

Rejection, New Grounds

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-7, 14, 15, and 17-22 are rejected under 35 U.S.C. 102(b) as being anticipated by Dzieglewska et al. (WO 98/51693, published November 19, 1998).

Dzieglewska et al. disclose a method of separating nucleic acid from a sample, comprising the steps:

a) bringing the sample containing the nucleated cells (eukaryotic cells, *see* page 4, lines 29-30) with a lysis solution containing at least a cellular component degrading enzyme and a surfactant (*see*

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page 11, lines 21 and 27, and the phrase, "any such method of combination of methods may be used");

b) bringing the sample containing nucleated cells into contact with a water-insoluble solid-phase carrier having an average particle size of 0.01 to 1000 μm (page 4, lines 7-10; page 9, lines 26-30) in the presence of a water-soluble organic solvent (page 6, lines 5-10) to adsorb and bind nucleic acids released from the nucleated cells onto the surface of the solid-phase carrier, thereby obtaining a solid-phase carrier having adsorbed nucleic acids (page 4, lines 4-5), and

c) separating the solid-phase carrier from the sample, thereby separating and purifying said nucleic acids (page 14, lines 31-35), thereby clearly anticipating claims 1 and 5.

With regard to claim 2, the cellular component-degrading enzyme is a protease (page 11, lines 26-29).

With regard to claims 3 and 14, a surfactant is SDS, also known as sodium dodecyl sulfate (page 11, line 20-21).

With regard to claim 4, the water-insoluble solid-phase carrier is glass, silica, latex or polymeric material (page 9, lines 17-18).

With regard to claim 6, the artisans elute the nucleic acids (page 15, lines 27-34).

With regard to claim 7, the artisans clearly contemplate a kit comprising the elements of the disclosed method (Abstract; page 19, line 12).

With regard to claims 15, 21, and 22, the artisans clearly state that for detergents, such as SDS, 0.5 to 15% detergents are to be employed (page 12, lines 18-19).

With regard to claims 17-19, the water-soluble organic solve is alcohol (page 6, line 9), more particularly, isopropanol or ethanol (page 9, line 16).

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With regard to claim 20, the concentration of the water-soluble organic solvent is from 50-100% by volume (page 6, lines 25-26).

Therefore, Dzieglewska et al. clearly anticipate the invention as claimed.

Claim Rejections - 35 USC § 103

The rejection of claim 7 under 35 U.S.C. 102(a) and (e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Belley et al. (U.S. Patent No. 6,469,159 B1, issued October 22, 2002, filed April 26, 1999), made in the Office Action mailed on January 13, 2006 is withdrawn in view of the Amendment received on March 16, 2006. Specifically, Belley et al. do not disclose a method involving a water-soluble organic solvent, thereby failing to teach all of the claimed limitations.

The rejection of claims 1, 2, and 4-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Belley et al. (U.S. Patent No. 6,469,159, issued October 22, 2002, filed April 26, 1999) in view of Caldarelli-Stefano et al. (Journal of Clinical Pathology, 1999, vol. 52, pages 158-160) as evidenced by Warburton et al. (Laboratory Procedures MFLP-90, April 1997, pages 1-2; Google® [online]. Retrieved on December 19, 2005 from Google®) made in the Office Action mailed on January 13, 2006 is withdrawn in view of the Amendment received on March 16, 2006.

Belley et al. do not disclose a method involving water-soluble organic solvent and the rest of the artisans do not cure this deficiency. Therefore, the rejection must fall.

Rejection, New Grounds

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 8-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dzieglewska et al. (WO 98/51693, published November 19, 1998) in view of Ekeze et al. (EP 0 795 751 A2, published September 17, 1997).

The teachings of Dzieglewska et al. have already been discussed above.

Dzieglewska et al., while explicitly contemplating that their method would be used in analyzing wide array of sample types, such as tissues, blood, blood-derived product, such as buffy coat (page 5, lines 9-10), does not explicitly teach well known methods involved in treatment of each types of samples, particularly, blood samples.

Ekeze et al. disclose a well-known method of isolating nucleic acid from a blood sample, wherein the blood sample is treated with ammonium chloride, particularly in the concentration of 50 mM (or 0.05 M) (see page 3, lines 11-12).

It would have been *prima facie* obvious to one of ordinary skill in the art to employ the teachings of Dzieglewska et al. for the purpose of isolating nucleic acids from blood samples, wherein the artisans would have been clearly motivated to completely lyse the red-blood cells via well-known ammonium chloride treatment, so as to isolate the intact white blood cells from which to isolate the nucleic acids from, as evidenced by Ekeze et al.

With regard to the determination of the optimal conditions for recovering maximum amount of white blood cells, involving temperatures and ammonium chloride concentration, such is considered to be optimizing well-known conditions involving routine optimization.

MPEP 2144.05(II)(A) discloses that, “differences in concentrations or temperature will not support patentability of subject matter encompassed by prior art unless there is evidence indicating such concentration or temperature is critical,” citing *In re Aller*, F.2d 454, 456, 105 USPQ 233, 235, (CCPA 1995).

Therefore, the invention as claimed is *prima facie* obvious over the cited references.

Claims 13 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dzieglewska et al. (WO 98/51693, published November 19, 1998) in view of Belley et al. (U.S. Patent No. 6,469,159, issued October 22, 2002, filed April 26, 1999¹).

The teachings of Dzieglewska et al. have already been discussed above.

Dzieglewska et al., while explicitly contemplating that their method would be used in analyzing wide array of sample types, such as tissues, blood, blood-derived product, such as buffy coat (page 5, lines 9-10), does not explicitly teach well known methods involved in treatment of each types of samples, particularly, tissues.

Belley et al. disclose a method of separating nucleic acid from paraffin embedded tissues (thus nucleated cells; *see* column 7, lines 45-46), wherein said method involves the steps: a) contacting the paraffin sample containing the nucleated cells with a lysis solution containing a protease (column 7, line 50; thus “a cellular component-degrading enzyme) and a surfactant (Tween20®; *see* column 7, line 49; column 4, lines 44-46; and claim 5).

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Belley et al. explicitly disclose that the conditions involving the extraction involving their reagents are “readily determinable” by those of ordinary skill in the art. In particular, Belley et al. disclose the use of protease in extracting nucleic acid from tissues, wherein the conditions involve an incubation of the sample with the enzyme at 70° to 100° Celsius (column 4, lines 50-51).

With regard to the concentration of the enzyme, and its purity, such is clearly within the purview of an ordinarily skilled artisan in the art of nucleic acid extraction/isolation, the conditions of which would purely involve routine optimization.

MPEP 2144.05(II)(A) discloses that, “differences in concentrations or temperature will not support patentability of subject matter encompassed by prior art unless there is evidence indicating such concentration or temperature is critical,” citing *In re Aller*, F.2d 454, 456, 105 USPQ 233, 235, (CCPA 1995).

Given the fact that the practice of employing proteases and temperature for extracting nucleic acids from tissue samples had been well known and established, finding an optimal concentration from which to operate from would only involve a routine experimentation of an ordinarily skilled artisan.

Therefore, the invention as claimed is *prima facie* obvious over the cited references.

Conclusion

No claims are allowed.

Inquiries

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Young J. Kim whose telephone number is (571) 272-0785. The Examiner is on flex-time schedule and can best be reached from 8:30 a.m. to 4:30 p.m. The Examiner can also

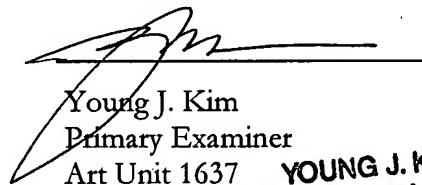
¹ Already of record.

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be reached via e-mail to Young.Kim@uspto.gov. However, the office cannot guarantee security through the e-mail system nor should official papers be transmitted through this route.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Dr. Gary Benzion, can be reached at (571) 272-0782.

Papers related to this application may be submitted to Art Unit 1637 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If applicant does submit a paper by FAX, the original copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office. All official documents must be sent to the Official Tech Center Fax number: (571) 273-8300. For Unofficial documents, faxes can be sent directly to the Examiner at (571) 273-0785. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-1600.


Young J. Kim
Primary Examiner
Art Unit 1637
5/30/2006
YOUNG J. KIM
PATENT EXAMINER

yjk